REMARKS/ARGUMENTS

This is in response to the Office Action mailed July 18, 2006 for the above-captioned application. Reconsideration and further examination are respectfully requested.

Claim 24 has been amended to independent form. This claim was only the subject of an objection, referenced on the cover sheet of the office action, but not elsewhere explained. It is believed that claim 24 should now be allowable.

Applicants respectfully request that the Examiner reconsider the restriction requirement in this case to the extent that it required the election of a single nucleic acid sequence. In this regard, Applicants respectfully point out that the MPEP § 802 indicates that election of up to 10 sequences in a single application is reasonable absent some showing that the sequences present unusual complications. This standard has plainly not been met here. Thus, recombination of claims directed to Seq. ID No. 2 is urged.

Claims 20-23, 29 and 30 stand rejected under 35 USC § 103 as unpatentable over the combination of Zhai et al in view of US Patent No. 5,773,291 and US Patent No. 6,080,727. Applicants respectfully traverse this rejection, and submit that the rejection is clearly based on the type of hindsight which is improper in a rejection under 35 USC § 103. Withdrawal of the rejection is therefore urged.

"Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination." *Carella v. Starlight Archery and Pro Line Co.*, 804 F.2d 135, 140, 231 USPQ 644, 647 (Fed. Cir. 1986) (citing *ACS Hosp. Syss., Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984)). "[T]he factual inquiry whether to combine references must be thorough and searching." *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1351-52, 60 USPQ2d 1001, 1008 (Fed. Cir. 2001).

Zhai, the principle reference in this case, relates to inducement of T cell immunity for treatment of melanoma in mammals. The Examiner acknowledges that Zhai does not disclose the specific antigens (tyrosinase or gp75) that are the subject of the dependent claims. In addition, Applicants point out that Zhai says noting about canine malignant melanoma which is also the subject of the present claims.

The '291 patent is cited for a teaching of expression of human typrosinase and gp75. The Examiner argues that there is motivation to use these vectors in the method of Zhai et al. because "it is well known in the art that tyrosinase and gp75, quite like gp100, is recognized as a TAA implicated in the development of cancer vaccines and the Zhai treatment is advantageous."

Applicants submit that the references of record simply do not support this statement. Reference is made by the Examiner to a single sentence in Zhai et al,. which indicates that the identification of genes encoding TAA "has opened new possibilities for the development of cancer vaccines." There is a marked lack of congruence between this speculation concerning opportunities and the examiner's statement of what is "well-known" and what is reasonably likely to successful.

Furthermore, none of the references relates to the treatment of canine malignant melanoma. The '727 patent can at best be said to provide support for the proposition that melanoma (as a general term) occurs in dogs, but since the reference has nothing to do with melanoma differentiation antigens (the antisense used is to the c-myc sequence) nothing further can be reasonably extracted from this reference. Melanoma in general, however, is not the same as canine malignant melanoma (CMM).

Attached are several documents which relate to CMM. In 1999, Modiano et al. stated that "Canine malignant melanoma is a rapidly metastatic disease that generally is incurable." In 2006, investigators at the University of California at Davis stated that "the fatality rate of this cancer is very high despite aggressive treatment with surgery, radiation therapy and chemotherapy." Similarly, the National Canine Cancer Foundation web site (http://www.wearethecure.org/melanoma.htm) observes that

> Melanoma occurs commonly in dogs with pigmented (dark) skin. Melanomas arise from pigment producing cells called melanocytes, which are responsible for coloring the skin. Any dog can be affected, but Gordon Setters, Standard and Miniature Schnauzers, Doberman Pinschers, and Scottish terriers, among others, are at increased risk to develop melanoma, suggesting that this disease may have a hereditary component. Melanomas can occur in areas of haired skin, where they usually form small, dark (brown to black) lumps, but can also appear as large, flat, wrinkled masses. Melanoma of the haired skin in dogs is usually a benign tumor, although it can cause severe discomfort. **In contrast, malignant melanoma, which develops in the mouth or in the distal limbs (usually the toenail beds), is an incurable disease.** These tumors have very often spread to distant parts of the body (metastasized) by the time they are first noticed, making complete surgical removal impossible.

The Examiner's failure to take into account that the claims are not directed merely to melanoma, but to the very aggressive and hard-to-treat disease CMM is a failure to properly consider the scope of the claimed invention. Nothing in the art cited suggests that this disease can be treated with xenogeneic differentiation antigens. Accordingly, the rejection should be withdrawn.

Furthermore, Zhai only discloses use of adenoviral vectors. Cancer antigens expressed in adenovirus and vaccinia virus are special cases. Even the self gene expressed in adenovirus and vaccinia gives immunity to cancer. For instance, Perricone et al. (Molecular Therapy 1:275-284, 2000) show that adenovirus vectors expressing either human and mouse gp100 inhibit tumor growth in mice. In addition, Overwijk et al. (PNAS 96:2092-2097, 1999) showed that vaccinia vector expressing mouse TRP-1 (also called TYRP1, gp75) inhibited mouse melanoma. Thus, in both cases the virus encoding the self gene inhibited growth of a mouse tumor. For plasmid DNA vaccines, DNA vaccination with the self-antigen does not result in tumor rejection. One needs the xenogeneic non-self DNA. The Zhai et al. manuscript shows xenogeneic gp100 works when delivered by the adenovirus, but this is a special type of vaccine (with substantial risks for use clinically) that also works for self-antigen. Thus, the Zhai et al. paper would not have predicted that xenogeneic plasmid DNA vaccine would work when self DNA vaccine did not. Thus, for this additional reason the application of Zhai to the claims in general, and to claim 30 in particular (which resides a non-viral plasmid vector) is not supportive of an obviousness rejection.

Respectfully submitted,

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Note: Performing your original search, ***"canine malignant melanoma"***, in PubMed will retrieve *12* citations.

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1: J Vet Intern Med. 1999 May-Jun;13(3):163-74. Related Articles, Links

The molecular basis of canine melanoma: pathogenesis and trends in diagnosis and therapy.

Modiano JF, **Ritt MG**, **Wojcieszyn J**.

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Melanoma is a common neoplastic disease of dogs with variable presentation and biological behavior. Canine malignant melanoma is a rapidly metastatic disease that generally is incurable. The loss of function of cellular safeguards built into the genetic program and of immune surveillance systems that cooperate to prevent tumor formation and progression appear to be important underlying causes of canine malignant melanoma. In effect, many existing cancer treatments restore the function of 1 or the other of these mechanisms. For example, chemotherapy and radiotherapy often kill tumor cells by initiating a genetic suicide mechanism (apoptosis), and immunotherapy initiates or enhances a response by the body's immune cells to identify and destroy cancer cells by mechanisms that rely on direct cytotoxicity or apoptotic cell death. Nevertheless, standard therapeutic approaches have not proved effective in treatment of canine malignant melanoma, with only marginal improvement in the outcome of dogs with this disease. The advantages of an improved understanding of the molecular basis of canine cancer are underscored by recent promising advances in diagnosis and in immunologic and genetic therapies that may help reduce the mortality of dogs affected with malignant melanoma.

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UC-Davis studies malignant melanoma in dogs

Aug 1, 2006
By: Jessica Tremayne
DVM Newsmagazine

DAVIS, CALIF. — Dr. Michael Kent, an investigator at the University of California-Davis, is exploring different drugs to help fight canine malignant melanoma.

The Morris Animal Foundation is providing a portion of the grant money necessary to conduct the research, which could unveil a way to make these types of tumors less resistant to treatment.

The fatality rate of this cancer is very high despite aggressive treatment with surgery, radiation therapy and chemotherapy.

"This type of cancer is fairly common and often fatal," Kent says. "We are testing drugs in cell lines developed from dogs with oral melanomas in combination with radiation."

The tumors often are found in dogs' mouths, nail beds or skin.

Seizures and difficulty breathing can occur if the cancer spreads.

Cancer of the oral cavity accounts for 6 percent of canine tumors, making it the fourth most-common neoplasm in dogs, and malignant melanoma accounts for 30-40 percent of all oral lesions, Kent says.

"Similar to the disease in people, malignant canine melanoma is a highly metastatic tumor with many patients not surviving more than six months post diagnosis," he adds. "Surgery in the oral cavity for melanomas often requires extensive procedures, such as maxillectomy, mandibulectomy and/or orbitectomy and is rarely used for lesions located in the caudal portion of the mouth due to a substantial increase in morbidity.

Even with radical surgical procedures, local recurrence rate ranges from 25-43 percent. With radiation therapy, up to 83 percent of dogs having a complete or partial response,

the time to regrowth or metastasis is often short lived with reported overall survival times of seven months.

Kent says if this work is successful, the next step will be to try these drugs in combination with radiation therapy.

The foundation is sponsoring the research for two years. Kent, in his sixth month of research, hopes the end result will improve the efficacy of treatment and lead to better tumor control.

About the Author

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Melanoma

Melanoma occurs commonly in dogs with pigmented (d skin. Melanomas arise from pigment producing cells cal melanocytes, which are responsible for coloring the ski dog can be affected, but Gordon Setters, Standard and Miniature Schnauzers, Doberman Pinschers, and Scottis terriers, among others, are at increased risk to develop melanoma, suggesting that this disease may have a he component. Melanomas can occur in areas of haired ski where they usually form small, dark (brown to black) lu but can also appear as large, flat, wrinkled masses. Mel of the haired skin in dogs is usually a benign tumor, alt can cause severe discomfort. In contrast, malignant melanoma, which develops in the mouth or in the dista (usually the toenail beds), is an incurable disease. Thes tumors have very often spread to distant parts of the b (metastasized) by the time they are first noticed, maki complete surgical removal impossible.

Radiation therapy can help extend the lives of affected but also is ineffective against tumor cells that have metastasized. Chemotherapy is also not considered cap adequately controlling canine malignant melanoma.

Melanoma seems to be uniquely responsive to immune therapies, and various novel approaches are under development to treat this disease.